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TITLE: University of Kansas Cancer Center Breast Tissue and Serum Repository Core Facility

PRINCIPAL INVESTIGATOR: Jonathan J. Li, Ph.D.

CONTRACTING ORGANIZATION: University of Kansas Medical Center
Kansas City, Kansas 66160-7700

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With the support of the U.S. Army Medical Research and Development, the University of Kansas Medical Center and the Kansas Cancer Institute has established a Breast Tissue and Serum Repository (BTSR) Core Facility, the first such facility in the lower Midwest. Funding of this core facility has served as the basis for its recent expansion to other female endocrine gynecologic cancers and the endocrine-associated male prostate cancer. The BTSR is fully supported by the Department of Surgery and Pathology, and will serve research needs not only at KU Medical Center, but to other institutions in the Kansas City Metropolitan area, and throughout the states of Kansas and Missouri. It is anticipated that in future years, the BTSR, with its systematic collection of normal and malignant tissues, including corresponding serum and lymphocyte samples, will serve as an increasingly important function for investigator-initiated cancer research studies.

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FOREWORD

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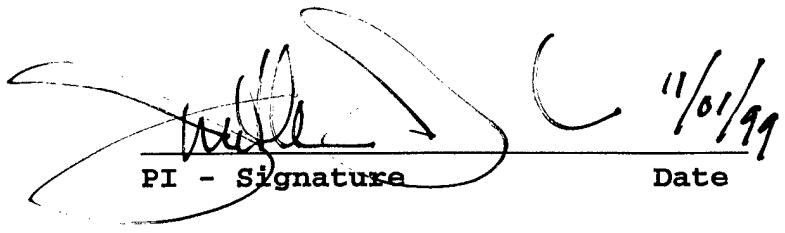
In conducting research using animals, the investigator(s) adhered to the "Guide for the Care and Use of Laboratory Animals," prepared by the Committee on Care and use of Laboratory Animals of the Institute of Laboratory Resources, national Research Council (NIH Publication No. 86-23, Revised 1985).

X For the protection of human subjects, the investigator(s) adhered to policies of applicable Federal Law 45 CFR 46.

N/A In conducting research utilizing recombinant DNA technology, the investigator(s) adhered to current guidelines promulgated by the National Institutes of Health.

N/A In the conduct of research utilizing recombinant DNA, the investigator(s) adhered to the NIH Guidelines for Research Involving Recombinant DNA Molecules.

X In the conduct of research involving hazardous organisms, the investigator(s) adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.



PI - Signature 11/01/99 Date

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INTRODUCTION

Breast cancer (BC) is the most prevalent of all cancer diseases in women throughout the world. In the USA, the risk of women developing BC by age 85 years is currently about one in eight. The cause(s) of BC and the means to predict who will develop it are currently not well-understood. Recognizing the cause(s) and possible susceptibility to BC are essential steps to the successful prevention of this prevalent disease in the future. Similarly, there is a paucity of knowledge related to early detection of BC, because screening procedures, while highly improved, do not allow detection of BC at the earliest and most curable stages. The development of the Breast Tissue and Serum Repository (BTSR) Core Facility at the Division of Etiology and Prevention of Hormonal Cancers (DEPHC), Kansas Cancer Institute (KCI) of the University of Kansas Medical Center (KUMC) has been an important step to address these issues at this institution.

A main focus of the Division of Etiology and Prevention of Hormonal Cancers (DEPHC) is to assist, complement, and expand ongoing programs, as well as to develop new ones related to the molecular biology and cytogenetics of hormone-related cancer research at KCI/KUMC. Although it is evident that the etiology of human BC is multifactorial, a central emphasis of the DEPHC is that hormones, particularly estrogens and progestins, play a critical role in BC causation, progression, and dependency, since it is increasingly apparent that both endogenous and exogenous estrogens and progesterional agents are critically involved in the etiology and development of human BC.

The BTSR's purpose is to facilitate investigator-initiated research to perform correlation studies on the incidence of possible premalignant and malignant breast lesions with genetic and variable biomarkers (e.g., receptors, hormones, cellular proteins, protooncogenes, tumor suppressor genes), and to assess the presence of potential carcinogens.

BODY

I. Background

With the funding provided, the BTSR has been operational for 53 months. Dr. Jonathan J. Li continues as Director, Dr. Sara Antonia Li is the Associate Director, Ms. Jodi Ballenger is the Biologist II, and Ms. Stephanie Parks was the secretary until June 25, 1999.

II. Experimental Methods

Patients

The BTSR biologist receives the daily surgical schedule for breast, endometrium, ovarian, and prostate surgeries. Three days before a patient is scheduled to have surgery, she/he is required to go to the Outpatient Laboratory to have her/his blood drawn for various presurgical tests. The BTSR biologist is stationed in the Outpatient Laboratory at the time of each of these appointments to be sure that extra blood is drawn and to label the blood vials with the proper outpatient laboratory labels, which include the patient's name and hospital patient identification number.

In addition, the BTSR biologist gives the patient consent forms for donating blood to the BTSR, asking the patient to sign them, and to complete the Personal Health History questionnaire. After the patient completes the appropriate questionnaire, the BTSR biologist writes the six-digit specimen-specific identification number on the upper right-hand corner of the front page of the questionnaire. Copies of the Request for Participation in the BTSR, Informed Consent, and Patient Questionnaires for Breast, Gynecological, and Prostate Surgery are included in the Appendix under Items 1 to 3. The patient questionnaire for gynecological surgeries (endometrium and ovarian cancer specimens) is identical to that used for breast cancer patients.

Tissue Samples

Breast, endometrium, and ovarian tissue samples for the KCI-BTSR are acquired from female patients undergoing either breast reductions, biopsies, lumpectomies, mastectomies, or hysterectomies and/or oophorectomies for malignant and nonmalignant conditions. Prostate tissue is collected from male patients undergoing prostectomies. Copies of the protocols for breast and prostate tissue procurement are included in the Appendix under Items 4 and 5.

All the specimens are handled in a timely fashion in order to preserve the integrity of the tissues appropriately. Normal, abnormal, and neoplastic tissues are placed on a frozen cutting board and delivered, within 10 min of excision, to the Surgical Pathology Laboratory. At the lab, a certified

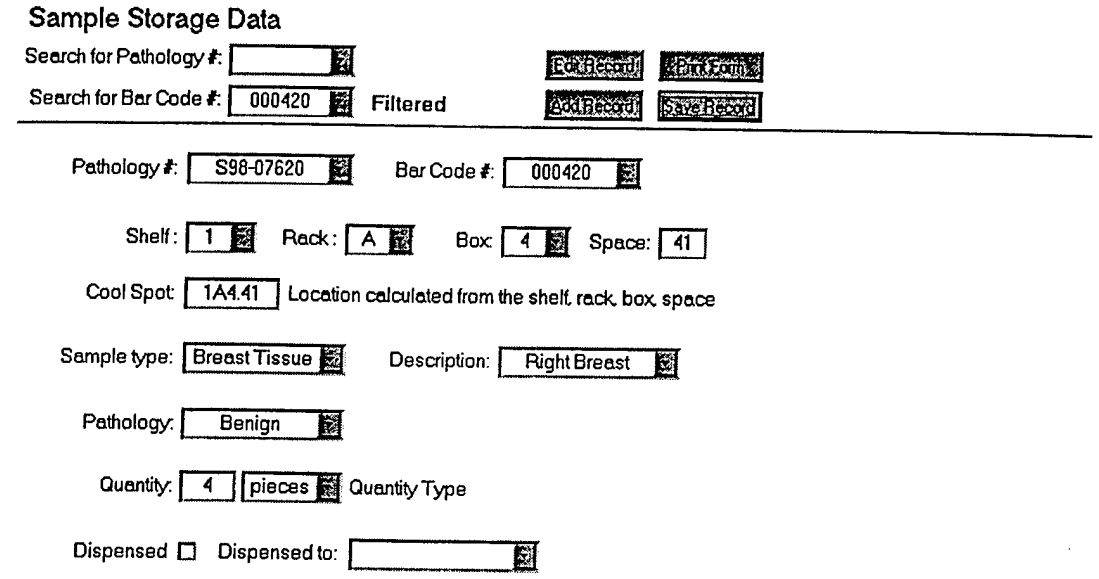
pathologist immediately evaluates the tumors, and frozen sections are prepared for diagnosis. When sufficient amount of tissue is available, the pathologist cuts tumor/normal tissue specimens for the BTSR biologist.

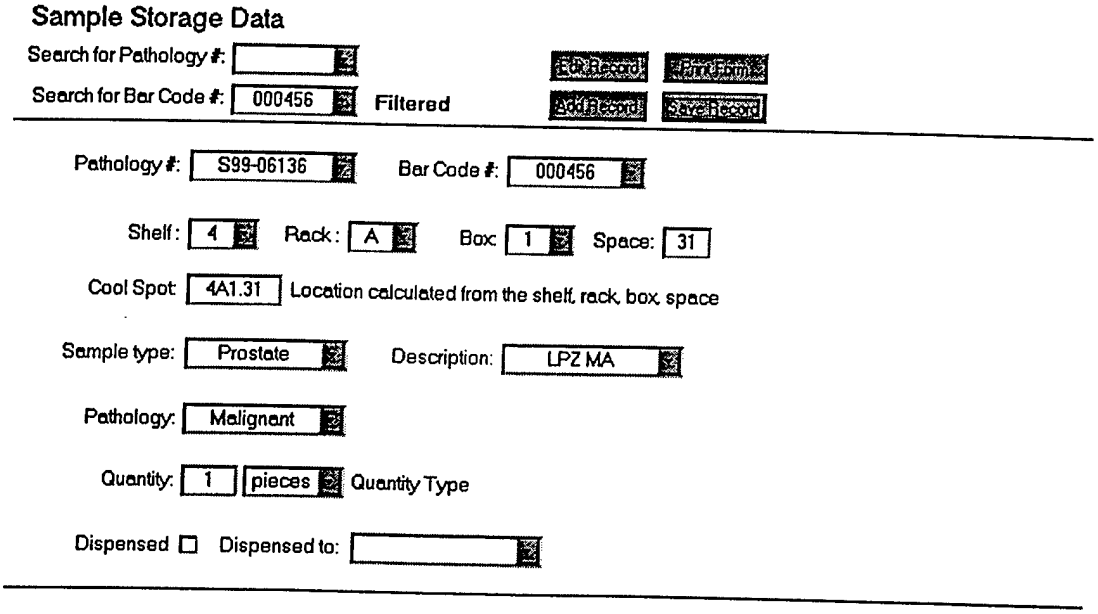
When the amount of tissue is adequate, one portion is allocated for frozen sections, and the remaining tissue is labeled with a proper bar-code label (specimen-specific identification number) and snap-frozen in a polypropylene container. Tissue samples destined for frozen sections are covered with tissue-embedding medium in a cryomold, placed in an airtight polypropylene container, similarly bar-code labeled, and snap-frozen immediately in an N_2 container before storage in the BTSR freezer.

Each specimen is assigned a unique six-digit specimen-specific identification number, which is assigned sequentially. The same bar-code number is used to identify each individual patient malignant and healthy adjacent tissues, and blood productss. All tissue aliquots derived from the same tissue are assigned the same six-digit number. This six-digit specimen-specific identification number is shown on the bar-code with which the biologist labels each container and slide.

Surgical Pathology requisition forms are computer generated by the Surgery Department and accompany the specimens when delivered to the Pathology Laboratory. The information in the forms includes: Hospital patient identification number, surgeon's name, patient's name and age, date of surgery, and site of specimen. In addition, Surgical Pathology personnel write the Surgical Pathology identification number on the requisition form, and the surgical pathologist measures the tumor before it is divided, indicating the size of the tumor in the report. The biologist records the BTSR specimen-specific identification number on the requisition form, makes a copy of this form, and takes the it to the BTSR along with the specimens. These data are entered into the BTSR database.

Examples of sample storage data for breast and prostate tissues.





The following tests are routinely carried out on all malignant breast biopsy samples at KUMC.

(1) A complete surgical pathology analysis, including size, tumor characteristics, histological type and grade, etc.
(2) Estrogen and progesterone receptor analysis.
(3) Immunostaining for p53 and HER-2/neu.
(4) Ploidy analysis by flow cytometry or image analysis.

BTSR personnel can retrieve the results of all these tests as soon as they are available and enter the information into the BTSR database, as described below in Cataloging and Storage. Estrogen and progesterone tumor status are obtained from the Clinical Laboratory and the ploidy analysis from the Flow Cytometry Laboratory, while the rest of the test results are obtained from the Surgical Pathology Department.

Serum Samples

Blood samples from both women and man undergoing tumor removal, and women at the KCI High Risk Breast Clinic are submitted to the BTSR.

Women who are considered at high risk for breast cancer are eligible to participate in the KCI High-Risk Breast Clinic. In general, eligible women include those between 30 and 55 years of age who have at least one of the following conditions: a first-degree relative who has had breast cancer, or, in herself, precancerous mastopathy or prior node-negative breast cancer in one breast.

The High-Risk Breast Clinic is located at the KU Cancer Center Comprehensive Outpatient Diagnostic and Treatment Center. During each patient's first visit to the clinic, blood is drawn for various medical tests. The BTSR biologist is responsible for securing the schedule of these visits in advance and advising the clinic to draw one extra vial of blood from each new patient for the BTSR. An identical procedure, described above, for securing the blood and completed questionnaire from breast surgery patients at the Outpatient Laboratory is followed for new patients seen at the High-Risk Breast Clinic.

When blood specimens are received at the BTSR, the biologist processes the blood before the specimens are cataloged and stored in the freezer. Copies of the protocols for serum and lymphocyte separation are in the Appendix as Item 6. Each container is labeled with the proper bar-code label and snap-frozen. The labels are scanned and the appropriate data entered.

The specimen-specific number on the bar-code label is assigned to all specimens obtained. When applicable, the six-digit identification number is identical to the number assigned to the tissue specimen for the same patient.

Lymphocyte Samples

The BTSR has the capacity to separate and freeze lymphocytes from peripheral blood when a special request is received. Blood is collected in heparin-containing tubes.

After all serum and lymphocytes samples are separated and labeled, they are stored in a -80°C freezer and the data regarding storage location in the Location Table of the database are recorded. The data include specimen identification number and sample location, including freezer shelf, box, and cubicle number. This allows the BTSR staff to locate all specimens quickly and efficiently.

Storage and Cataloging

When a tissue sample is received at the BTSR, the specimen bar codes are scanned into the Biopsy Table or the Healthy Adjacent Table, as appropriate. The unique hospital patient identification number, the date when the specimen was received at the BTSR, the hospital of origin, the total amount of tissue, the surgical date, and all other data shown on the surgical requisition form that accompanies each specimen are recorded and stored in a computer.

All specimen-specific and patient-specific data are maintained in the computerized Repository Database Management system. In the Repository Database, the key fields are the unique specimen number, the hospital patient identification number, and the Surgical Pathology identification number. This combination serves as a unique patient identifier. Any or all of the tables within the database are linked using these three fields.

When a patient questionnaire is delivered to the BTSR, it is labeled with the appropriate bar code. The six-digit identification number matches those of the specimens from the same patient. The questionnaire labels are then scanned and the data entered into the Demographic/Life Style Table. The data requested include demographic, physical, and lifestyle information. Specifically, questions concern age, racial/ethnic background, marital status, religion, weight, height, education, occupation, family income, family history of cancer, reproductive status, and alcohol/tobacco history. To maintain confidentiality, all questionnaires are filed and locked up in a secure location after the data are entered into the database.

RESULTS

The total number of breast, endometrial, ovarian, and prostate tissue specimens with accompanying blood products (serum, lymphocytes, or plasma) and histology blocks is summarized on Table 1.

Table 1. Specimen Update 10/22/99

BREAST TISSUE			
	Malignant	Non-Malignant	Normal
Total Samples	86	129	24
Blood Products*	55	50	1
Histology Blocks	56	81	17
Complete Sets	32	33	1

* Blood products: Serum, lymphocytes, or plasma samples

ENDOMETRIAL TISSUE		
	Malignant	Non-Malignant
Total Samples	21	60
Blood Products*	15	54
Histology Blocks	17	31
Complete Sets	12	29

* Blood products: Serum, lymphocytes, or plasma samples

OVARIAN TISSUE		
	Malignant	Non-Malignant
Total Samples	17	75
Blood Products*	16	67
Histology Blocks	11	50
Complete Sets	11	49

* Blood products: Serum, lymphocytes, or plasma samples

PROSTATE TISSUE			
	Malignant	Non-Malignant	Normal
Total Samples	7	6	1
Blood Products*	7	6	1
Complete Sets	7	6	1

* Blood products: Serum, lymphocytes, or plasma samples

The BTSR has collected plasma in addition to serum and lymphocytes. The collection of these specimens is summarized on Table 2. For surgical patients from whom tissue is not available, blood is still collected for the BTSR. However, it is not always available due to patient refusal.

Table 2. Blood Products Update 10/22/99

BREAST			
	Total Samples	Malignant	Non-Malignant
Serum Samples	173	105	70
Lymphocyte Samples	157	93	63
Plasma Samples	62	37	27

ENDOMETRIUM			
	Total Samples	Malignant	Non-Malignant
Serum Samples	69	16	56
Lymphocyte Samples	67	16	54
Plasma Samples	21	8	14

OVARY			
	Total Samples	Malignant	Non-Malignant
Serum Samples	82	18	67
Lymphocyte Samples	79	18	64
Plasma Samples	30	8	22

PROSTATE			
	Total Samples	Malignant	Non-Malignant
Serum Samples	9	7	6
Lymphocyte Samples	9	7	6
Plasma Samples	3	3	0

To use the specimens collected by the BTSR, KUMC and outside investigators submit proposal to the BTSR. When received, the proposals are reviewed by the BTSR Committee on Human Tissue Specimen Usage for approval. The list of the members of the committee has been included in the Appendix as Item 7. The following investigators are currently approved for specimen use.

Investigator	% Estimated Use				Research Support
	1996	1997	1998	1999	
Jonathan J. Li, Ph.D. (KUMC) *Sara Antonia Li*, Ph.D. (KUMC)	5%	5%	5%	5%	NCI 5 R01 CA 58030-04 NCI 5 R01 CA 58030-05 NCI 1 R01 CA 64047-03
Walter T. Imagawa, Ph.D. (KUMC)	10%	10%	10%		ACS RD-55 NCI CA 68414-01 USAMRMC BC960604
Gregory Reed, Ph.D. (KUMC)	10%	10%	10%	10%	Dept. of Pharmacology institutional funds
Carol Fabian, M.D. (KUMC)	15%	15%	15%		NCI P01 CA 72094 NCI U01 CA 72296 NCI MAA NCI CN 45593-32 NCI N01 CN 65024-32
Dr. Lin Tao (Uni. Missouri – Kansas City)		10%	10%		NIH KS-34647
Leslie Heckert, Ph.D. (KUMC)		10%	10%		Kansas Cancer Institute institutional funds
Tsuneo Suzuki, M.D., Ph.D. (KUMC)		10%	10%		NIH P01 CA 54474
Eric Elsinghorst, Ph.D. (Uni. Kansas – Lawrence		5%	5%		Dept. of Microbiology institutional funds
Wade Bushman, M.D., Ph.D. (N.W. Univ. Medical School Chicago)				3%	NIH funding

CONCLUSIONS

With the support of the U.S. Army Medical Research and Development, the University of Kansas Medical Center and the Kansas Cancer Institute has established a Breast Tissue and Serum Repository (BTSR) Core Facility, the first such facility in the lower Midwest. Funding of this core facility has served as the basis for its recent expansion to other female endocrine gynecologic cancers and the endocrine-associated male prostate cancer. The BTSR is fully supported by the Departments of Surgery and Pathology, and will serve research needs not only at KU Medical Center, but to other institutions in the Kansas City Metropolitan area, and throughout the states of Kansas and Missouri. It is anticipated that in future years, the BTSR, with its systematic collection of normal and malignant tissues, including corresponding serum and lymphocyte samples, will serve as an increasingly important function for investigator-initiated cancer research studies.

The University of Kansas Medical

Kansas Cancer Institute

To: All Patients Scheduled for Breast Surgery

A Request for Participation in the Tissue and Serum Repository

The University of Kansas Medical Center has established a Tissue and Serum Repository. One main purpose of this Repository is to document, cryopreserve, and store serum and samples of breast tissue obtained from patients undergoing surgical procedures on the breast. This Repository will serve as a necessary and needed resource for epidemiologists, and clinical and basic scientists who need a comprehensive and well documented storehouse of serum and breast tissue for research in breast biology and breast cancer. Specimens from the Repository will be allocated primarily to investigators in Kansas, Missouri, and the Southern Great Plains States after proper institutional review of requests. It is hoped that this Repository will enhance research in normal breast biology and breast cancer at the University of Kansas and regionally and assist in the search for better methods for early detection, diagnosis, and treatment of breast cancer.

The University of Kansas Medical Center asks for your participation in the Repository. Participation is voluntary and whether or not you choose to participate, the quality of your care by your physicians will not be affected in any way now or in the future. If you agree to participate, patient confidentiality will be strictly observed. Participation will entail the completion of a health history questionnaire, the signing of consent forms for the use of blood and tissue for research, and the donation of blood and a sample of the tissue removed during surgery. The questionnaire and consent forms are included in this packet. If you agree to participate, then bring this packet with completed questionnaire and consent forms (signed in the presence of a witness) with you on your surgery day. The packet may be left at the patient holding area of Same Day Surgery. Any questions you may have about the forms should be addressed to the Repository technician prior to the scheduled surgery date. A blood sample will be drawn, either during a scheduled clinic appointment prior to surgery, in the operating room, or during your post-operative appointment. Tissue samples, if available, will be provided to the Repository from the Surgical Pathology Laboratory where all tissues are sent for postsurgical examination.

Thank you for your cooperation,

Jonathan J. Li, Ph.D.
Director Division of Etiology and Prevention of Hormonal Cancers
Director Tissue and Serum Repository
University of Kansas Cancer Institute
University of Kansas Medical Center

TISSUE and SERUM REPOSITORY INFORMED CONSENT

INTRODUCTION

I understand that as a person who will be undergoing biopsy or oncologic-related surgery I am being invited to participate in the University of Kansas Cancer Institute Tissue and Serum Repository. This repository will be located at the University of Kansas Medical Center.

PURPOSE

The purpose of this repository is to store tissue, blood sera, plasma, and lymphocytes and make these materials available to cancer research investigators at the University of Kansas Medical Center and to other cancer research investigators in the region. The researchers will be studying what causes cancer, who will develop this disease, and how cancer can be detected at an early stage. The tissue and blood will be used for research using biological, biochemical, and molecular approaches.

PROCEDURE

My participation in this repository will require two extra vials of blood being drawn in the Outpatient Laboratory or in the Cancer Center Outpatient Clinic or in the operating room. This is equivalent to approximately 4 teaspoons of blood. Extra tissue, if available, will be provided to the Repository by the Laboratory of Surgical Pathology. In addition, I will be asked to complete a Personal Health History Questionnaire. It will take about 15 minutes to complete the questionnaire.

RISKS

Drawing blood may cause pain, bruising and very rarely infection.

BENEFITS

This repository will probably not benefit me directly. This effort may help society learn more about cancer.

PAYMENT TO SUBJECTS

I will not be paid for contributing to the Tissue and Serum Repository.

COSTS

There will be no cost to me for contributing to the Repository.

INSTITUTIONAL DISCLAIMER STATEMENT

"You are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. If I believe I have been injured as a result of participating in research, I should contact the Office of Legal Counsel, University of Kansas Medical Center, Kansas City, Kansas 66160-7101."

CONFIDENTIALITY

I understand the investigators will keep confidential all research related records and information from this study. However, I realize that sometimes the investigators will need to let others look at records of my participation. I agree to let representatives of the Department of the Army, U.S. Army Medical Research and Development Command and representatives of other research investigators who use my

tissue and/or serum in their research see my records. I understand that Repository investigators will not reveal my identity in any published material related to the Tissue and Serum Repository.

USE

I understand that there is a possibility that the blood and tissue samples which I am providing under this study may also be used in other research studies and could potentially have some commercial applicability.

QUESTIONS

I have read the information in this form. The investigators have answered my questions to my satisfaction. I know if I have any more questions after signing this form, I may contact the Director of the Tissue and Serum Repository, Dr. Jonathan J. Li at (913) 588-4742. If I have any questions about my rights as a research subject I may call (913) 588-1240 or write the Human Subjects Committee, University of Kansas Medical Center, 5012 Wescoe, 3901 Rainbow Blvd., Kansas City, Kansas, 66160-7700.

CONSENT

The investigator(s) have given me information about what will be done to me by participating in the Repository and research studies. They also told me how it will be done, what I will have to do, and the purposes of the Repository and research. They have informed me about any inconvenience and discomfort or risks that I may experience due to my participation. They explained to me how my participation may affect me or my health. I agree to contribute blood and tissue to the Repository as a research subject. I am aware that I may refuse to answer any questions on the questionnaire or I may refuse any part of the research study. I understand that refusing to participate in the Repository will have no effect upon the medical care or treatment I receive in the future. I understand that the investigators will give me a copy of this form to keep for my records.

_____
Type/Print Subject's name

_____ _____
Date Subject's Signature

WITNESS (to subject's signature of document)

_____ _____
Date Witness Signature

RESPONSIBLE INVESTIGATOR (Director of the Tissue and Serum Repository)

9/15/11 _____
Date Responsible Investigator's Signature

BREAST SERUM REPOSITORY

I voluntarily and freely donate any and all serum samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.

_____
Type/Print Subject's Name

_____ _____
Date Subject's Signature

_____ _____
Date Witness' Signature

GENERAL INFORMATION

Today's Date:_____

1. *Please write in your birth date:*_____
(Month, Day, Year)

2. *What is your height?*_____

3. *What is your current weight?*_____

4. *How would you describe yourself?*

White/Caucasian.....	1	
Black/African-American.....	2	(circle one number)
Latino/Hispanic/Mexican-American.....	3	
Asian/Oriental/Pacific Islander.....	4	
American Indian/Native Alaskan.....	5	
Other: Specify_____	6	

5. *What is your religion?*

Catholic.....	1	
Protestant.....	2	
Mormon.....	3	(circle one number)
Seventh Day Adventist.....	4	
Baptist.....	5	
Jewish.....	6	
None.....	7	
Other: Specify_____	8	

6. *What is your current occupation? If you are no longer employed, then what was your last occupation?*_____

7. *What is your current marital status?*

Single.....	1	
Married.....	2	(circle one number)
Divorced.....	3	
Widowed.....	4	

8. *Where were you born?*_____
City State Country

9. *Where is your current permanent residence?*_____
City County State

10. *When did you start residing at your current permanent residence?*_____
(Month, Day, Year)

*11. Where did you reside the longest up to the age of 18?*_____
City State Country

*12. If foreign born, when did you immigrate to the United States?*_____
Year

13. How much school did you complete?

Some elementary	1	
Elementary	2	(circle one number)
Some high school	3	
High school diploma/GED	4	
Vocational/Technical school	5	
Some college	6	
College degree	7	
Some post-graduate	8	
Post-graduate degree	9	

14. To the best of your knowledge, what is your approximate annual combined household income, including investment income, retirement income, etc.?

Under $15,000	1	
$15,000-$25,000	2	(circle one number)
$25,000-$35,000	3	
$35,000-$50,000	4	
$50,000-$100,000	5	
Over $100,000	6	

*15. What is the number of individuals supported by this income?*_____

HEALTH AND MEDICAL HISTORY

*16. How old were you when you first started having your period?*_____

17. Have you ever experienced an irregular menstrual cycle?

Yes	1	(circle one number)
No	2	

*18. If you answered **no** to the above question, please skip to question #19.*
*If you answered **yes** to the above question, please describe how your menstrual cycle was irregular.*_____
*How long was it irregular?*_____
Have you ever taken prescription drugs to correct irregularities in your cycle?

Yes	1	(circle one number)
No	2	

18.(continued) Please list the drug(s) you have taken and by each one, also, list the number of months and/or years you took the drug(s).

Name of the drug	***Months/Years taken***
_____	_____
_____	_____
_____	_____
_____	_____

19. Are you still menstruating?

Yes..... 1 (circle one number)
No..... 2

*If you answered **no** to the above question, at what age did you experience menopause?*_____

20. Have you had a hysterectomy?

Yes..... 1 (circle one number)
No..... 2

*If you answered **yes** to the above question, at what age did you have a hysterectomy?*_____

21. Have you had your ovaries removed?

Yes..... 1 (circle one number)
No..... 2
Not sure..... 3

*If you answered **yes** to the above question, did you have one or both ovaries removed?*

One ovary removed..... 1
Both ovaries removed..... 2 (circle one number)
Not sure..... 3

*22. Are you a **DES** daughter?*

Yes..... 1 (circle one number)
No..... 2

23. Have you ever used birth control pills?

Yes..... 1 (circle one number)
No..... 2

*If you answered **no** to the above question, please skip to question #24.*
*If you answered **yes** to the above question, how old were you when you first began using the pill?*_____
*How many months or years did you use the pill?*_____ (month/year)-*circle one*
Please list the name of the birth control pill(s) that you used. If you know the composition and dose, please include that information with your list.

Name of the drug	***Composition***	***Dose***
_____	_____	_____
_____	_____	_____
_____	_____	_____

24. Have you ever been pregnant?

Yes..... 1 (circle one number)

No..... 2

*If you answered **yes** to the above question, please answer the following questions. If any of these questions do not apply to you, you may place an N/A in the blank.*

a. *How many live births have you had?*_____

*b. How many miscarriages have you had?*_____*At what age(s)?*_____

*c. How many abortions have you had?*_____*At what age(s)?*_____

*Number of weeks gestation at time of abortion(s)?*_____

Were oral contraceptives prescribed?

Yes..... 1 (circle one number)

No..... 2

*If you answered **yes** to the above question, how long did you take the oral contraceptives?*_____

*d. How old were you when your first child was born?*_____

*e. How old were you when your last child was born?*_____

f. Did you breast-feed any of your children?

Yes..... 1

No..... 2

*If you answered **yes** to the above question, how many total months did you breast-feed all of your children?*_____

*How old were you when you first breast-fed a child?*_____

25. Have you ever taken drugs to induce ovulation (for infertility)?

Yes..... 1 (circle one number)

No..... 2

*If you answered **no** to the above question, please skip to question # 26.*

*If you answered **yes** to the above question, how old were you when you first began using a drug to induce ovulation?*_____

*How many months or years did you use them?*_____

Please list the name of the drug(s) that you used.

Name of the drug(s)

_____

_____

26. Have you ever used hormone replacement medications?

Yes..... 1 (circle one number)

No..... 2

*If you answered **no** to the above question, please skip to question # 27.*

*If you answered **yes** to the above question, how old were you when you first began using hormone replacement drugs?*_____

*How many months or years did you use them?*_____ (month/year)-*circle one*

Which hormone replacement medication(s) have you used?

Estrogen (Premarin) & Progesterone (Provera)..... 1

Estrogen (Premarin)..... 2 (circle all that apply)

Other: Specify_____ 3

27. Have you ever taken a prescription drug on a regular basis for a year or more?

Yes..... 1 (circle one number)
No..... 2

*If you answered **no** to the above question, please skip to question #28.*
*If you answered **yes** to the above question, please list the name of the drug(s) that you used and for what purpose the drug(s) was taken.*

Name of the drug	***Purpose***
_____	_____
_____	_____
_____	_____

28. Have you ever had a breast biopsy?

Yes..... 1
No..... 2

*If you answered **no** to the above question, please skip to question # 29.*
*If you answered **yes** to the above question, how many?_____*
List the month and year you had the biopsy(s).

Month/Year	***Month/Year***	***Month/Year***	***Month/Year***
_____	_____	_____	_____

29. Are you scheduled to have a breast biopsy?

Yes..... 1 (circle one number)
No..... 2

30. Have you ever had any other cancer-related surgeries?

Yes..... 1 (circle one number)
No..... 2

*If you answered **no** to the above question, please skip to question # 31.*
*If you answered **yes** to the above question, please list the type of surgery and the month/year the surgery took place.*

Surgery Type	***Month/Year***
_____	_____
_____	_____
_____	_____

31. Have you ever been diagnosed with benign breast disease?

Yes..... 1 (circle one number)
No..... 2

32. Has a <u>blood</u> relative ever been diagnosed with breast cancer?

Yes..... 1
No..... 2
Not Sure..... 3

*If you answered **no** to the above question, please skip to question # 33.*

32. *(continued) If you answered **yes** , what is the relationship of this person to you?*
(circle all that apply)

Mother.....	1	Maternal Aunt.....	6
Sister.....	2	Paternal Aunt.....	7
Daughter.....	3	Other:Specify*_____	8
Maternal Grandmother.....	4	_____	
Paternal Grandmother.....	5	_____	

*Please note maternal/paternal

33. *Have you ever been diagnosed with any major disease(s)?*
Yes..... 1
No..... 2
*If you answered **yes** to the above question, please indicate the major disease(s).*
_____

DIET AND LIFESTYLE

34. *Have you ever consumed alcoholic beverages at least once a week for one year or more?*
Yes..... 1 (circle one number)
No..... 2
*If you answered **no** to the above question, please skip to question #35.*

*If you answered **yes** to the above question, how old were you when you first started drinking regularly?*_____
Do you still drink?
Yes..... 1 (circle one number)
No..... 2
Approximately how many of each alcoholic beverage (one beverage=12 ounces beer, 4 ounces wine, or 1.5 ounces of liquor) ***do/did** you drink in an average week?*
Beer____Wine____Liquor_____

*If you are no longer drinking, at what age did you stop?*_____

35. *Do you drink coffee?*
Yes..... 1 (circle one number)
No..... 2
*If you answered **no** to the above question, please skip to question #36.*

*If you answered **yes** to the above question, how many cups of coffee do you drink of the following types listed?*
Regular _____ (per day/per week)-*circle one*
Decaffeinated _____ (per day/ per week)-*circle one*

36. Do you drink cola beverages?

Yes..... 1 (circle one number)

No..... 2

*If you answered **no** to the above question, please skip to question #37.*

*If you answered **yes** to the above question,how many 12 ounce servings do you drink of the following types listed.*

Regular _____ (per day/per week)-*circle one*

Caffeine Free _____ (per day/per week)-*circle one*

37. Do you drink tea?

Yes..... 1

No..... 2

*If you answered **no** to the above question, please skip to question #38.*

*If you answered **yes** to the above question, how many cups of tea do you drink of the following types listed?*

Green_____(per day/per week)-*circle one*

Black_____(per day/per week)-*circle one*

Herbal_____(per day/per week)-*circle one*

38. Are you a vegetarian?

Yes..... 1 (circle one number)

No..... 2

39. Do you currently smoke?

Yes..... 1 (circle one number)

No..... 2

*If you answered **no**, did you <u>ever</u> smoke?*

Yes..... 1 (circle one number)

No..... 2

*If you answered **yes** to either question above, at what age did you start smoking?*_____

*At what age did you quit smoking?*_____

*How many packs do/did you smoke?*_____(per day/ per week)-*circle one*

Thank you for your cooperation in completing this form.

The University of Kansas Medica

Kansas Cancer Institute

To: All Patients Scheduled for Gynecological Surgery

A Request for Participation in the Tissue and Serum Repository

The University of Kansas Medical Center has established a Tissue and Serum Repository. One main purpose of this Repository is to document, cryopreserve, and store serum and samples of endometrial and ovarian tissue obtained from patients undergoing gynecological surgery. This Repository will serve as a necessary and needed resource for epidemiologists, and clinical and basic scientists who need a comprehensive and well documented storehouse of serum and gynecological tissue for research in endometrial/ovarian biology and endometrial/ovarian cancer. Specimens from the Repository will be allocated primarily to investigators in Kansas, Missouri, and the Southern Great Plains States after proper institutional review of requests. It is hoped that this Repository will enhance research in normal endometrial/ovarian biology and endometrial/ovarian cancer at the University of Kansas and regionally and assist in the search for better methods for early detection, diagnosis, and treatment of endometrial and ovarian cancers.

The University of Kansas Medical Center asks for your participation in the Repository. Participation is voluntary and whether or not you choose to participate, the quality of your care by your physicians will not be affected in any way now or in the future. If you agree to participate, patient confidentiality will be strictly observed. Participation will entail the completion of a health history questionnaire, the signing of consent forms for the use of blood and tissue for research, and the donation of blood and a sample of the tissue removed during surgery. The questionnaire and consent forms are included in this packet. If you agree to participate, then bring this packet with completed questionnaire and consent forms (signed in the presence of a witness) with you on your surgery day. The packet may be left at the patient holding area of Same Day Surgery. Any questions you may have about the forms should be addressed to the Repository technician prior to the scheduled surgery date. A blood sample will be drawn, either during a scheduled clinic appointment prior to surgery, in the operating room, or during your post-operative appointment. Tissue samples, if available, will be provided to the Repository from the Surgical Pathology Laboratory where all tissues are sent for postsurgical examination.

Thank you for your cooperation,

Jonathan J. Li, Ph.D.
Director Division of Etiology and Prevention of Hormonal Cancers
Director Tissue and Serum Repository
University of Kansas Cancer Institute
University of Kansas Medical Center

ENDOMETRIAL AND OVARIAN TISSUE REPOSITORY

I voluntarily and freely donate any and all tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.

_____
Type/Print Subject's Name

_____ _____
Date Subject's Signature

_____ _____
Date Witness' Signature

ENDOMETRIAL AND OVARIAN SERUM REPOSITORY

I voluntarily and freely donate any and all serum samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.

_____
Type/Print Subject's Name

_____ _____
Date Subject's Signature

_____ _____
Date Witness' Signature

The University of Kansas Medica

Kansas Cancer Institute

To: All Patients Scheduled for Prostate Surgery

A Request for Participation in the Tissue and Serum Repository

The University of Kansas Medical Center has established a Tissue and Serum Repository. One main purpose of this Repository is to document, cryopreserve, and store serum and samples of prostate tissue obtained from patients undergoing surgical procedures on the prostate. This Repository will serve as a necessary and needed resource for epidemiologists, and clinical and basic scientists who need a comprehensive and well documented storehouse of serum and prostate tissue for research in prostate biology and prostate cancer. Specimens from the Repository will be allocated primarily to investigators in Kansas, Missouri, and the Southern Great Plains States after proper institutional review of requests. It is hoped that this Repository will enhance research in normal prostate biology and prostate cancer at the University of Kansas and regionally and assist in the search for better methods for early detection, diagnosis, and treatment of prostate cancer.

The University of Kansas Medical Center asks for your participation in the Repository. Participation is voluntary and whether or not you choose to participate, the quality of your care by your physicians will not be affected in any way now or in the future. If you agree to participate, patient confidentiality will be strictly observed. Participation will entail the completion of a health history questionnaire, the signing of consent forms for the use of blood and tissue for research, and the donation of blood and a sample of the tissue removed during surgery. The questionnaire and consent forms are included in this packet. If you agree to participate, then bring this packet with completed questionnaire and consent forms (signed in the presence of a witness) with you on your surgery date. The packet may be left at the Cancer Center front desk. Any questions you may have about the forms should be addressed to the Repository technician prior to the surgery date. A blood sample will be drawn,either during your scheduled clinic appointment prior to surgery or during your post-operative appointment. Tissue samples, if available, will be provided to the Repository from the Surgical Pathology Laboratory where all tissues are sent for postsurgical examination.

Thank you for your cooperation,

Jonathan J. Li, Ph.D.
Director Division of Etiology and Prevention of Hormonal Cancers
Director Tissue and Serum Repository
University of Kansas Cancer Institute
University of Kansas Medical Center

TISSUE and SERUM REPOSITORY INFORMED CONSENT

INTRODUCTION

I understand that as a person who will be undergoing biopsy or oncologic-related surgery I am being invited to participate in the University of Kansas Cancer Institute Tissue and Serum Repository. This repository will be located at the University of Kansas Medical Center.

PURPOSE

The purpose of this repository is to store tissue, blood sera, plasma, and lymphocytes and make these materials available to cancer research investigators at the University of Kansas Medical Center and to other cancer research investigators in the region. The researchers will be studying what causes cancer, who will develop this disease, and how cancer can be detected at an early stage. The tissue and blood will be used for research using biological, biochemical, and molecular approaches.

PROCEDURE

My participation in this repository will require two extra vials of blood being drawn in the Outpatient Laboratory or in the Cancer Center Outpatient Clinic or in the operating room. This is equivalent to approximately 4 teaspoons of blood. Extra tissue, if available, will be provided to the Repository by the Laboratory of Surgical Pathology. In addition, I will be asked to complete a Personal Health History Questionnaire. It will take about 15 minutes to complete the questionnaire.

RISKS

Drawing blood may cause pain, bruising and very rarely infection.

BENEFITS

This repository will probably not benefit me directly. This effort may help society learn more about cancer.

PAYMENT TO SUBJECTS

I will not be paid for contributing to the Tissue and Serum Repository.

COSTS

There will be no cost to me for contributing to the Repository.

INSTITUTIONAL DISCLAIMER STATEMENT

"You are authorized all necessary medical care for injury or disease which is the proximate result of your participation in this research. If I believe I have been injured as a result of participating in research, I should contact the Office of Legal Counsel, University of Kansas Medical Center, Kansas City, Kansas 66160-7101."

CONFIDENTIALITY

I understand the investigators will keep confidential all research related records and information from this study. However, I realize that sometimes the investigators will need to let others look at records of my participation. I agree to let representatives of the Department of the Army, U.S. Army Medical Research and Development Command and representatives of other research investigators who use my

tissue and/or serum in their research see my records. I understand that Repository investigatorÕs will not reveal my identity in any published material related to the Tissue and Serum Repository.

USE

I understand that there is a possibility that the blood and tissue samples which I am providing under this study may also be used in other research studies and could potentially have some commercial applicability.

QUESTIONS

I have read the information in this form. The investigators have answered my questions to my satisfaction. I know if I have any more questions after signing this form, I may contact the Director of the Tissue and Serum Repository, Dr. Jonathan J. Li at (913) 588-4742. If I have any questions about my rights as a research subject I may call (913) 588-1240 or write the Human Subjects Committee, University of Kansas Medical Center, 5012 Wescoe, 3901 Rainbow Blvd., Kansas City, Kansas, 66160-7700.

CONSENT

The investigator(s) have given me information about what will be done to me by participating in the Repository and research studies. They also told me how it will be done, what I will have to do, and the purposes of the Repository and research. They have informed me about any inconvenience and discomfort or risks that I may experience due to my participation. They explained to me how my participation may affect me or my health. I agree to contribute blood and tissue to the Repository as a research subject. I am aware that I may refuse to answer any questions on the questionnaire or I may refuse any part of the research study. I understand that refusing to participate in the Repository will have no effect upon the medical care or treatment I receive in the future. I understand that the investigators will give me a copy of this form to keep for my records.

_____
Type/Print Subject's name

_____ _____
Date Subject's Signature

WITNESS (to subject's signature of document)

_____ _____
Date Witness Signature

RESPONSIBLE INVESTIGATOR (Director of the Tissue and Serum Repository).

11/25/1998 _____
Date Responsible Investigator's Signature

PROSTATE TISSUE REPOSITORY

I voluntarily and freely donate any and all tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.

_____
Type/Print Subject's Name

_____ _____
Date Subject's Signature

_____ _____
Date Witness' Signature

PROSTATE SERUM REPOSITORY

I voluntarily and freely donate any and all serum samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.

_____
Type/Print Subject's Name

_____ _____
Date Subject's Signature

_____ _____
Date Witness' Signature

KANSAS CANCER INSTITUTE
TISSUE AND SERUM REPOSITORY

PROSTATE CANCER QUESTIONNAIRE

DO NOT WRITE YOUR NAME ANYWHERE ON THIS SURVEY

1. *The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?*
(Circle 1, 2, or 3 on each line)

		Yes Limited A Lot	Yes Limited A Little	No Not Limited At All
a.	**Vigorous activities**, such as running, lifting heavy objects, participating in strenuous sports.....	1	2	3
b.	**Moderate activities**, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf.....	1	2	3
c.	Lifting or carrying groceries.....	1	2	3
d.	Climbing **several** flights of stairs.....	1	2	3
e.	Climbing **one** flight of stairs.....	1	2	3
f.	Bending, kneeling or stooping.....	1	2	3
g.	Walking **more than a mile**.....	1	2	3
h.	Walking **several blocks**.....	1	2	3
i.	Walking **one block**.....	1	2	3
j.	Bathing or dressing yourself.....	1	2	3

2. *During the past **4wks**, have you had any of the following problems with your work or other regular daily activities as a result of your **physical health**?*
(please answer yes or no for each question by circling 1 or 2 on each line)

		Yes	No
a.	Cut down the **amount of time** you spent on work or other activities.....	1	2
b.	**Accomplished less** than you would like.....	1	2
c.	Were limited in the **kind** of work or other activities.....	1	2
d.	Had **difficulty** performing the work or other activities (for example, it took extra effort).....	1	2

3. *During the **past 4 wks**, have you had any of the following problems with your work or other regular daily activities as a result of an **emotional problems**, such as feeling depressed or anxious?*
(Please answer yes or no for each question by circling 1 or 2 on each line)

		Yes	No
a.	Cut down the **amount of time** you spent on work or other activities.....	1	2
b.	**Accomplished less** than you would like.....	1	2
c.	Didn't do work or other activities as **carefully** as usual.....	1	2

4. *These questions are about how you feel and how things have been with you **during the past 4wks**. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time **during the past 4 wks**.....*
(Circle one number on each line)

		All of the Time	Most of the Time	A Good part of Time	Some of the Time	A Little of the Time	None of the Time
a.	Did you feel full of pep?.....	1	2	3	4	5	6
b.	Have you been a very nervous person?.....	1	2	3	4	5	6
c.	Have you felt so down in the dumps that nothing could cheer you up?.....	1	2	3	4	5	6
d.	Have you felt calm and peaceful?.....	1	2	3	4	5	6
e.	Did you have a lot of energy?.....	1	2	3	4	5	6
f.	Have you felt downhearted and blue?.....	1	2	3	4	5	6
g.	Did you feel worn out?.....	1	2	3	4	5	6
h.	Have you been a happy person?.....	1	2	3	4	5	6
i.	Did you feel tired?.....	1	2	3	4	5	6

5. *During the **past 4 wks**, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?*

All of the time.....1

Most of the time.....2 *(Circle one number)*

Some of the time.....3

A little of the time.....4

None of the time.....5

6. *During the **past 4 wks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?*

Not at all.....1

Slightly.....2 *(Circle one number)*

Moderately.....3

Quite a bit.....4

Extremely.....5

7. *How much bodily pain have you had during the **past 4 wks**?*

None.....1

Very mild.....2 (Circle one number)

Mild.....3

Moderate.....4

Severe.....5

Very Severe.....6

8. *During the **past 4 wks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?*

Not at all.....1

Slightly.....2 (Circle one number)

Moderately.....3

Quite a bit.....4

Extremely.....5

9. *Please choose the answer that best describes how true or false each of the following statements is for you.*
(Circle one number on each line)

		Definitely True	Mostly True	Not Sure	Mostly False	Definitely False
a.	I seem to get sick a little easier than other people	1	2	3	4	5
b.	I am as healthy as anyone I know	1	2	3	4	5
c.	I expect my health to get worse	1	2	3	4	5
d.	My health is excellent	1	2	3	4	5

10. In general, would you say your health is:

Excellent.....1
Very good.....2 (circle one number)
Good.....3
Fair.....4
Poor.....5

*11. **Compared to one year ago**, how would you rate your health in general now?*

Much better now than one year ago.....1
Somewhat better now than one year ago.....2 (circle one number)
About the same.....3
Somewhat worse now than one year ago.....4
Much worse now than one year ago.....5

URINARY FUNCTION:
This section is about your urinary habits. Please **consider only the last 4 wks**.

12. *Over the past 4 wks, how often have you leaked urine?*

Every day.....1
About once a week.....2 (circle one number)
Less than once a week.....3
Not at all.....4

13. *Which of the following best describes your urinary control* ***during the last 4 wks?***

No control whatsoever.....1
Frequent dribbling.....2 (circle one number)
Occasional dribbling.....3
Total control.....4

14. *How many pads or adult diapers per day did you usually use to control leakage during the last 4* ***wks?***

3 or more pads per day.....1
1-2 pads per day.....2 (circle one number)
No pads.....3

15. *How big a problem, if any, has each of the following been for you?*
(circle one number on each line)

	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem
a. Dripping urine or wetting your pants.....0		1	2	3	4
b. Urine leakage interfering with your sexual activity.....0		1	2	3	4

16. *Overall, how big a problem has your urinary function been for you* ***during the last 4 wks?***

No problem.....1
Very small problem.....2 (circle one number)
Small problem.....3
Moderate problem.....4
Big problem.....5

BOWEL HABITS:
The next section is about your bowel habits and abdominal pain.
Please consider **only the last 4 wks.**

17. How often have you had rectal urgency (felt like I had to pass stool, but did not) during the last 4wks?

More than once a day.....1
About once a day.....2 (circle one number)
More than once a week.....3
About once a week.....4
Never.....5

18. How often have you had stools (bowel movements) that were loose or liquid (no form, watery, mushy,) during the last 4wks?

Never.....1
Rarely.....2 (circle one number)
About half the time.....3
Usually.....4
Always.....5

19. How much distress have your bowel movements caused you during the last 4 wks?

Severe distress.....1
Moderate distress.....2 (circle one number)
Little distress.....3
No distress.....4

20. How often have you had crampy pain in your abdomen or pelvis during the last 4 wks?

Several times a day.....1
About once a day.....2 (circle one number)
Several times a week.....3
About once a week.....4
About once this month.....5
Rarely or never.....6

21. Overall, how big a problem have your bowel habits been for you during the last 4 wks?

Big problem.....1
Moderate problem.....2 (circle one number)
Small problem.....3
Very small problem.....4
No problem.....5

SEXUAL HABITS:
The next section is about your sexual function and sexual satisfaction. Many of the questions are very personal, but they will help us understand the important issues that you face every day. Remember, YOUR NAME DOES NOT APPEAR ANYWHERE ON THIS SURVEY. Please answer honestly about **the last 4 wks only.**

22. *How would you rate each of the following during the last 4 wks?*
(circle one number on each line)

	Very Poor	Poor	Fair	Good	Very Good
a. Your level of sexual desire?..... 1		2	3	4	5
b. Your ability to have an erection?.....1		2	3	4	5
c. Your ability to reach orgasm (climax)?.....1		2	3	4	5

23. *How would you describe the ususal QUALITY of your erections?*
None at all.....1
Not firm enough for any sexual activity.....2 (circle one number)
Firm enough for masturbation and foreplay only.....3
Firm enough for intercourse.....4

24. *How would you describe the FREQUENCY of your erections?*
I **never** had an erection when I wanted one.....1
I had an erection **less than half** the time I wanted one.....2 (circle one number)
I had an erection **about half** the time I wanted one.....3
I had an erection **more than half** the time I wanted one.....4
I had an erection **whenever** I wanted one.....5

25. *How often have you awakened in the morning or night with an erection?*
Never.....1
Seldom (less than 25% of the time).....2 (circle one number)
Not often (less than half the time).....3
Often (more than half the time).....4
Very often (more than 75% of the time).....5

26. *During the last **4 wks** did you have vaginal or anal intercourse?*

No.....1
Yes, Once.....2 (circle one number)
Yes, More than once.....3

27. *Overall, how would you rate your ability to function sexually during the last 4 wks?*

Very Poor.....1
Poor.....2 (circle one number)
Fair.....3
Good.....4
Very Good.....5

28. *Overall, how big a problem has your sexual function been for you during the last 4 wks?*

No problem.....1
Very small problem.....2 (circle one number)
Small problem.....3
Moderate problem.....4
Big problem.....5

29. *Overall, how satisfied are you with the treatment you received for your prostate cancer?*

Extremely dissatisfied.....1
Dissatisfied.....2 (circle one number)
Uncertain.....3
Satisfied.....4
Extremely satisfied.....5

THANK YOU VERY MUCH!!!

FINAL SECTION:
These last questions are about your household and your general medical history. These items are very important for our research. Please answer honestly, and DO NOT WRITE YOUR NAME ANYWHERE ON THIS SURVEY.

1. *How old were you on your last birthday?*

   _____ years

2. *How do you describe yourself?*

   White/Caucasian (not Latino/Hispanic).....1
   Black/African-American (not Latino/Hispanic).....2 (circle one number)
   Latino/Hispanic/Mexican-American.....3
   Asian/Oriental/Pacific Islander.....4
   American Indian/Native Alaskan.....5

   Other: Specify_____.....6

3. *Which of the following best describes your current relationship?*

   Living with spouse or partner.....1
   In a significant relationship, but not living together.....2 (circle one number)
   Not in a significant relationship.....3

4. *What is your current marital status?*

   Never married.....1
   Married.....2 (circle one number)
   Separated.....3
   Divorced.....4
   Widowed.....5

5. *Are you now working at a paying job?*

   Yes, full-fime.....1
   Yes, part-time.....2 (circle one number)
   No, but looking for a job.....3
   No, retired.....4

6. *Do you smoke cigarettes?*

   No.....1 (circle one number)
   Yes.....2

Have you ever had any of the following treatments for prostate cancer?
(Please circle yes or no for every item)

	N0	Yes	
Radical prostatectomy (surgery to remove prostate)	1	2	Mth/yr of surgery_____
Radiation	1	2	Mth/yr completed_____
Orchiectomy (removal of testicles)	1	2	Mth/yr of surgery_____
Lupron/Zoladex shots	1	2	
Flutamide pills	1	2	

Other: Specify_____

*Have you **ever** had any of the following medical conditions:*
(please circle yes or no for every item)

	Yes	No
Diabetes	1	2
Heart attack, chest pain	1	2
Stroke	1	2
Amputation	1	2
Circulation problems in legs/feet	1	2
Asthma, emphysema, breathing problems	1	2
Stomach ulcer, irritable bowel	1	2
Kidney disease	1	2
Major depression	1	2
Seizures	1	2
Alcoholism or alcohol problems	1	2
Drug problems	1	2

How much school did you complete?

Grade school of less.....1
Some high school or technical school.....2
High school or technical school graduate.....3
Some college.....4
College graduate.....5
Graduate or professional school after college.....6

What is your approximate annual combined household income?

Zero.....1
Less than $5,000m but not zero.....2
$5,000 - $10,000.....3
$10,000 - $20,000.....4
$20,000 - $30,000.....5
$30,000 - $50,000.....6
$50,000 - $75,000.....7
More than $75,000.....8

THANK YOU VERY MUCH!!!!

Protocol for Breast Tissue Procu...

Tissue and Serum Repository
Kansas Cancer Institute
University of Kansas Medical Center

I. BREAST CLINIC

A. BREAST SURGERY IS SCHEDULED

1. Clinic staff contacts TSR Coordinator
   a) Office extension: **4766**
   b) Pager number: **917-6604**

2. TSR Coordinator will consent patient in clinic
   a) Information packet/Health History Questionnaire
   b) Explanation of the Repository
   c) Consent forms signed by participating patient
   d) Participant receives copies of signed consents

3. TSR Coordinator will place patient information in the Repository Tracker
   a) Name of patient
   b) Hospital ID number
   c) Date of surgery
   d) Procedure type (biopsy,lumpectomy,mastectomy)

4. Blood samples are collected from participant in either the Cancer Center or the operating room
   a) Serum Separator Vial---10 mL marble top
   b) ACD Solution A Vial---10 mL yellow top

5. Blood samples are transported to the TSR laboratory for processing
   a) TSR Coordinator will transport vials in an insulated container
   b) Blood is processed, stored, and cataloged according to laboratory protocols

6. Health History Questionnaire
   a) Patient may complete this questionnaire at home
   b) Questionnaire and any consents may be returned in Same Day Surgery on the scheduled surgery day
      i) Must be returned in the TSR envelope marked with the 'CONFIDENTIAL' label
      ii) TSR Coordinator will pick-up the envelope in SDS from a predetermined location

II. SURGERY

A. BLOOD COLLECTION

1. TSR Coordinator will be dressed in appropriate OR attire

2. TSR Coordinator will bring two blood collection tubes to the operating room
   a) Collect blood samples from only those patients who haven't donated blood, but have consented
   b) Anesthesiologist will collect two vials of blood from patient
      i) Serum Separator Vial---10 mL marble top
      ii) ACD Solution A Vial---10 mL yellow top

2. Blood samples are transported to the TSR laboratory for processing.
   a) TSR Coordinator will transport vials in an insulated container
   b) Blood is processed, stored, and cataloged according to laboratory protocols

B. TISSUE COLLECTION

1. TSR Coordinator will meet with the OR staff at beginning of surgery
   a) Remind staff to place the removed tissue in saline, not formalin

2. TSR Coordinator will meet with resident in Surgical Pathology who will be handling the case
   a) Leave instructions to be contacted at time tissue is received by Surgical Pathology
   b) TSR Coordinator should also exercise the habit of checking with Surgical Pathology from time to time, so as not to miss the opportunity to obtain tissue

3. Equipment for tissue procurement*
   a) 3 x 4 inch Zip-lock baggies
   b) Baggies with fold down tops
   c) Embedding molds for histology blocks
      i) Pre-labeled with freezer space number (1 to 16)
   d) Sharpie pen
   e) Gloves
   f) *Equipment should be stocked in Surgical Pathology in a small container marked for TSR use only

4. Attempt to obtain both malignant tissue and adjacent benign tissue from patients with a pre-operative diagnosis of breast cancer

5. Cut small, 1 gram size pieces with a clean razor blade

6. Place the tissue samples into a baggie without a zip-lock in a single layer

7. Snap-Freeze in liquid nitrogen used by Surgical Pathology by lowering the tissue with a pair of long forceps

8. Place the frozen tissue in a nearby cryostat

9. Place the frozen tissue (in the baggie) into a *pre-labeled* zip-lock bag
   a) Malignant or Benign
   b) Right or Left breast
   c) Number of samples
   d) Name of patient
   e) Surgical Pathology number

10. If a histology block will be made, place the baggie back into the cryostat

11. Prepare one histology block per breast, if enough tissue is available
   a) Place a tissue sample in a pre-labeled mold with OCT medium
   b) Cover with OCT and freeze over liquid nitrogen
      i)Use a lowering device supplied by Surgical Pathology
   c) Place the histology block with the frozen tissue and store in the -70°C freezer until transport

12. Use the TSR igloo cooler to transport the tissue on ice from Surgical pathology to the TSR laboratory

Protocol for Prostate Tissue Procurement

Tissue and Serum Repository
Kansas Cancer Institute
University of Kansas Medical Center

I. UROLOGY CLINIC

A. PROSTATECTOMY IS SCHEDULED

1. Assisting nurse contacts TSR Coordinator
   a) Office extension: **4766**
   b) Pager number: **917-6604**

2. TSR Coordinator will consent patient in clinic
   a) Information packet/Quality of Life Survey (QOL only for prostatectomy pts.)
   b) Explanation of the Repository
   c) Consent forms signed by participating patient
   d) Participant receives copies of signed consents

3. TSR Coordinator will place patient information in the Repository Tracker
   a) Name of patient
   b) Hospital ID number
   c) Date of surgery
   d) Procedure type (RRP, RPP, Cysto)

4. TSR Coordinator and attending nurse begin filling out clinical forms (for prostatectomy patients only)
   a) Registration
   b) Staging
   c) Prostate Ultrasound TRUS Report

5. TSR label will be placed on new participant's clinic file
   a) Bright label (green) will signify a TSR participant

6. Resident notifies TSR Coordinator once clinical forms (1a.-1c.) are completed
   a) Office extension: **4766**, if no answer, leave voice mail
   b) The resident may leave the forms in the urology clinic or the Urology department in predetermined locations

7. Quality of Life Survey
   a) Patient will complete this survey and return to assisting nurse in

urology clinic

b) Patient may also return QOL and any consents to Same Day Surgery on scheduled surgery day
    i) Must be returned in the TSR envelope marked with the 'CONFIDENTIAL' label
    ii) TSR Coordinator will pick-up the envelope in SDS or the urology clinic from a predetermined location

II. SURGERY

A. BLOOD COLLECTION

1. TSR Coordinator will be dressed in appropriate OR attire

2. TSR Coordinator will bring two blood collection tubes to the operating room
    a) Anesthesiologist will collect two vials of blood from patient
        i) Serum Separator Vial---10 mL marble top
        ii) ACD Solution A Vial---10 mL yellow top

3. Blood samples are transported to the TSR laboratory for processing
    a) TSR Coordinator will transport vials in an insulated container
    b) Blood is processed, stored, cataloged according to laboratory protocols

B. TISSUE COLLECTION

1. OR staff will notify TSR Coordinator approximately 20 minutes prior to the removal of the prostate

2. TSR Coordinator will be dressed in appropriate OR attire

3. TSR Coordinator will bring tissue collection items to OR
    a) Dry ice and liquid nitrogen
    b) 2 Acu-Punch biopsy instruments
    c) 4 Pre-labeled 2 mL cryovials
        i) Barcode label
        ii) Hand written barcode
        iii) Hand written coolspot
        iv) Numbered 1-4

d) Extra cryovials for any additional punch biopsies
e) Cryomarker to label any additional vials with subsequent number
f) Prostatectomy Specimen Log form (PSL)
    i) Tracks the locale of each punch biopsy from the prostate
    ii) One punch biopsy per vial
g) Radical Prostatectomy Pelvic Lymphadenectomy form (RPPL)
h) Gloves

4. Surgeon removes prostate; single cut is made through the mid portion, exposing two mirror image halves from which separate specimens can be harvested
    a) Prostate specimens obtained with an Acu-Punch biopsy instrument by the surgeon
    b) TSR Coordinator wears gloves and opens first cryovial to receive specimen from surgeon
    c) Cryovial containing the specimen is immediately placed in liquid nitrogen
    d) TSR Coordinator notes the prostate specimen locale on the PSL
    e) TSR Coordinator opens next cryovial and the same process is repeated
5. RPPL form is given to an attending resident to complete for TSR files
    a) Form delivered in a bright green envelope
    b) Resident contacts TSR Coordinator once form is completed
    c) Resident may leave the forms in bright green envelope in the urology clinic or the Urology department in predetermined locations

6. TSR will transport blood samples and tissue back to the TSR laboratory for processing, storage, and cataloging

Tissue and Serum Repository

Kansas Cancer Institute
University of Kansas Medical Center

Procurement of Prostate Tissue For the Sonic Hedgehog and Gli Study Northwestern University Medical School

I. PREPARE FIXATIVES & EtOH

A. PARAFORMALDEHYDE

1. Prepare fresh 4% PFA the morning of scheduled surgery

2. PFA recipe located in TSR Laboratory Protocols manual

B. FORMALIN

1. Obtain formalin in Surgical Pathology Laboratory

C. EtOH

1. Prepare a 70% EtOH solution for tissues to be placed after fixation

II. LABEL SCINTILLATION VIALS FOR FIXATIVES & EtOH

A. USE COLOR CODING LABELS (Avery 05473)

B. PLACE LABELS ON THE LIDS OF (8) VIALS

1. Red(2)
   a) Label one-FORMALIN/TUMOR
   b) Label other-FORMALIN/TUMOR/EtOH

2. Blue(2)
   a) Label one-FORMALIN/BENIGN
   b) Label other-FORMALIN/BENIGN/EtOH

3. Green(2)
   a) Label one-PFA/TUMOR
   b) Label other-PFA/TUMOR/EtOH

4. Yellow(2)
   a) Label one-PFA/BENIGN
   b) Label other-PFA/BENIGN/EtOH

C. PLACE FIXATIVES & EtOH IN LABELED VIALS

III. LABEL (2) CRYOVIALS FOR SNAP-FROZEN TISSUES

A. USE 2.0 mL GREEN-CAPPED CRYOVIALS

B. LABEL(1) VIAL-TUMOR

C. LABEL (1) VIAL-BENIGN

D. LABEL BOTH VIALS WITH BARCODE

IV. PROSTATECTOMY SURGERY

A. TISSUE COLLECTION

1. Surgeon will biopsy a region of the prostate, which upon gross diagnosis is malignant

2. Surgeon will take a small portion of the biopsy and cut into thirds, 3mm x 3mm samples
   a) One sample should be placed in pre-labeled 2 mL cryovial marked TUMOR *(green-capped)*
      i. Snap-freeze in liquid nitrogen
      ii. Snap-frozen samples will be designated with patient barcode, an 'S' for snap-frozen, followed by a 'T' for tumor (**123-S-T** is an example)
   b) One sample should be placed in the *red* pre-labeled vial marked FORMALIN/TUMOR
   c) One sample should be placed in the *green* pre-labeled vial marked PFA/TUMOR
   d) Remaining portion of tissue is frozen for Dr. Thrasher's study.*(See original protocol)*

3. Surgeon will biopsy a region of the prostate, which upon gross diagnosis is benign

4. Surgeon will take a small portion of the biopsy and cut into thirds, 3mm x 3mm samples

   a) One sample should be placed in pre-labeled 2 mL cryovial marked BENIGN *(green-capped)*
      i. Snap-freeze in liquid nitrogen
      ii. Snap-frozen samples will be designated with patient barcode, an 'S' for snap-frozen, followed by a 'B' for benign (**123-S-B** is an example)
   b) One sample should be placed in the *blue* pre-labeled vial marked FORMALIN/BENIGN
   c) One sample should be placed the *yellow* pre-labeled vial marked PFA/BENIGN
   d) Remaining portion of tissue is frozen for Dr. Thrasher's study.*(See original protocol)*

5. Fix the tissues for 45 minutes, then place in corresponding EtOH vials---store in refrigerator (4°C) until processed/embedded

6. Place the snap-frozen tissues in the freezer for temporary storage

V. TISSUE PROCESSING AND EMBEDDING

A. PREPARATION FOR SURGICAL PATHOLOGY

1. Label (4) 1.5 mL microtest tubes
   a) Patient barcode number
   b) PFA or Formalin
   c) Tumor or Benign

2. Transfer tissue to corresponding microtest tube
   a) Use clean forceps

3. Tissues should be kept at 4°C until transported to Pathology

4. Tissues will be transported to Pathology on Fridays

5. Surgical Pathology staff will label cassettes
   a) Patient barcode number
   b) 'P' for Paraformaldehyde-fixed; or 'F' for Formalin-fixed
   c) 'T' for Tumor tissue; or 'B' for Benign tissue
   d) Example: '123-P-T' for barcode 123, PFA-fixed, Tumor
   e) Tissue will be processed and embedded

6. Surgical Pathology staff will contact TSR Coordinator for pick-up

7. Embedded tissues will be transported to the TSR laboratory for storage at 4°C

VI. SHIPPING TISSUE

A. CONTACT AMERICAN ONE COURIER

1. Tissue will be shipped out after every tenth patient

2. Call the day before scheduled pick-up
   a) Do not ship out over a weekend

3. Phone number: 1-800-445-9995

4. Always ship snap-frozen tissue with a freeze-thaw indicator

B. CONTACT CHICAGO

1. Call Chicago at time of pick-up

2. Phone number: 1-312-908-8606

C. CHICAGO RECEIVES TISSUE

1. TSR is contacted immediately; report given on condition of tissue

Protocol for Serum Separation
Tissue and Serum Repository

Kansas Cancer Institute
University of Kansas Medical Center

Collect blood sample in a 10 mL Serum Separation tube. Keep the sample at room temperature for 1-2 hours, then follow this procedure:

1. Centrifuge at 1500 rpm for 15 minutes @ 4°C
2. Aliquot 1.5 mL serum into chilled cryovials which have been labeled with the assigned barcode and coolspot location
3. Freeze at -80°C
4. Note the coolspot locations, and aliquots in the database and patient file

Protocol for Lymphocyte Separation
Tissue and Serum Repository
Kansas Cancer Institute
University of Kansas Medical Center

Collect blood sample in a 10 mL ACD tube and follow this procedure:

- In 4 separate 15 mL centrifuge tubes, pipet 3 mL LSM.
- In a 50 mL Falcon tube dilute blood in equal volume of Hank's (8 mL).
- Layer ~ 4 mL of diluted blood into each of the 15 mL tubes w/ LSM.
- Centrifuge @ 1380 rpm for 23 minutes.
- Aspirate lymphocyte layer from each tube (plus ½ of the LSM layer below it).
- Pipet the lymphocytes to one 15 mL centrifuge tube.
- Add equal volume of Hank's (~ 5 mL). Cap tightly and invert gently 2 times.
- Centrifuge @ 1000 rpm for 10 minutes. (This is the 1st rinsing step.)
- Decant supernantant, leaving the pellet. Add 5 mL Hank's and resuspend pellet.
- Centrifuge @ 1000 rpm for 10 minutes. (This is the 2nd rinsing step.)
- Using a 5 mL pipet, draw off the supernatant being careful not to disturb the pellet.
- Resuspend the pellet in 0.5 mL Hank's.
- Pipet the cell solution into a pre-labeled cryovial, noting the amount minus 20 microliters.

  Before freezing cells, follow the instructions below to determine cell count.
- Note the coolspot location, and aliquots in the database and patient file

Determing Cell Count

In a 1 mL eppendorf tube, stain 20 microliters of cell solution with 180 microliters of crystal violet stain. Be sure to vortex gently (setting 4) for 20 seconds. Load the hemocytometer and count the number of cells in the middle square in *both* grids. Determine number of cells by averaging those 2 counts. Here's the formula:

$$\textbf{Total \# cells per mm3} = \frac{\text{number of cells}^* \times 10 \text{ (depth)} \times 10 \text{ (dilution factor)}}{(1)^* \text{ mm2}}$$

*Remember, for example, if 4 outer squares are counted in each grid, be sure to divide that count by 4 (mm2) in the formula.

Committee on Human Tissue Specimen Usa

Tissue and Serum Repository
Kansas Cancer Institute
University of Kansas Medical Center

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